

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**BLUE CROSS BLUE SHIELD
ASSOCIATION, *ET AL.***

PLAINTIFFS,

V.

GLAXOSMITHKLINE LLC,

DEFENDANT.

CIVIL ACTION NO. 2:13-CV-4663-JS

REDACTED FILING

**DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO
EXCLUDE EXPERT TESTIMONY OF PHILIP RUSS, DRS. DAVID KESSLER,
MATTHEW PERRI, STEPHEN SCHONDELMAYER, AND RENA CONTI**

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I. INTRODUCTION

Plaintiffs seek to recover billions they paid for 17 GSK drugs manufactured at a plant in Cidra, Puerto Rico (the “At-Issue Drugs”), claiming that these drugs were “worthless” because GSK violated current Good Manufacturing Practices (“cGMP”) and that, had plaintiffs known of the violations, they would not have paid for the drugs. Plaintiffs proffer the testimony of five experts, but, as discussed below, each report overreaches in important ways and some or all of their testimony should be excluded under well-established *Daubert* case law. In summary form, the experts’ failures are as follows:

EXPERT	SUBJECT MATTER	GROUND FOR EXCLUSION
Mr. Philip Russ	Current Good Manufacturing Practices	Fit; likely to mislead jury
Dr. David Kessler	Current Good Manufacturing Practices	Legal opinion; Reliability / no standard or methodology
Dr. Matthew Perri	Marketing	Reliability / no standard or methodology; Fit
Dr. Stephen Schondelmeyer	Economics	Reliability / no standard or methodology
Dr. Rena Conti	Economics/Damages	Legal opinion; Reliability / no standard or methodology

II. LEGAL STANDARD

The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In relevant part, the Court must determine whether: (i) the method employed by the expert to reach his or her conclusions is sufficiently reliable; and (ii) the testimony will assist the trier of fact, through the application of specialized expertise, to understand the evidence or

determine a fact in issue. *See Daubert*, 509 U.S. 579; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999) (trial judge’s gatekeeping function “applies not only to testimony based on ‘scientific’ knowledge, but also to testimony based on ‘technical’ and ‘other specialized’ knowledge.”). Plaintiffs bear the burden of establishing that each of their experts’ testimony satisfies these elements, referred to as “reliability” and “fit.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994). As gatekeeper, “[a] trial court has broad discretion to . . . exclude the testimony of a qualified expert.” *Serrano v. Cowles*, Civ. No. 06-5075, 2008 U.S. Dist. LEXIS 74506, at *4 (E.D. Pa. Sept. 26, 2008).

III. ARGUMENT

A. The Expert Testimony of Mr. Philip Russ Should Be Excluded Because it is Irrelevant and Likely to Mislead the Trier of Fact

The “pertinent inquiry” to be addressed by the trier of fact is whether plaintiffs can “prove that the nature of GSK’s [cGMP] violations had a material impact on the drugs for which they paid.” 11/9/16 Order, p. 11 [Dkt. 105]. Thus, plaintiffs must prove the At-Issue Drugs *were* materially impacted by cGMP violations. [REDACTED]

[REDACTED] That opinion is irrelevant to the Court’s inquiry and would only confuse or mislead.

Under *Daubert*, expert testimony should be excluded when it “does not fit the question before the Court” because it “would not aid, and might confuse,” the trier of fact. *Leese v. Lockheed Martin Corp.*, 6 F. Supp. 3d 546, 554 (D.N.J. 2014) (excluding expert whose damages analysis did not fit the question before the court of what loss of value the plaintiffs suffered). Because Mr. Russ opines on the wrong question, the Court should exercise its gatekeeper function and exclude his opinions.

The FDA has explained that determining the impact of cGMP violations on drugs is a context-specific task:

The impact of CGMP violations depends on the nature of those violations and on the specific drugs involved. A drug manufactured in violation of CGMP may still meet its labelled specifications, and the risk that the drug is unsafe or ineffective could be minimal.

See FDA, Facts About the Current Good Manufacturing Practices (CGMPs) (Ex. 1).

A series of horizontal black bars of varying lengths, representing redacted text. The bars are arranged in a list-like fashion, with some bars being longer than others, suggesting different levels of redaction or different types of information being withheld. The bars are solid black and have no text or other markings on them.

In the case

demonstrate, “material noncompliance” with cGMPs does not mean there is a “material impact” to any product.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For example, one of the two products FDA seized from Cidra was Paxil CR, a controlled-release drug. At the same time, Cidra also manufactured Paxil IR, an immediate-release version not subject to the seizure, but which plaintiffs now claim was materially impacted and thus “worthless.” To avoid confusion between the products, FDA released a statement advising patients that they could take Paxil IR “with confidence.” (*See* Ex. 6). [REDACTED]

[REDACTED]

[REDACTED]

Ultimately, the issue before the Court is not whether there were cGMP issues at Cidra – it is undisputed that the FDA identified cGMP deficiencies. [REDACTED]

[REDACTED] Rather, the issue is which (if any) of 17 At-Issue Drugs were “materially impacted” by the cGMP issues as would be necessary to have caused economic injury to plaintiffs. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Court’s gatekeeper function includes ensuring a “fit” between the expert’s opinion and the question relevant to the case in order to avoid the jury confusion that would otherwise certainly result. Here, Mr. Russ’s opinion should be excluded because it does not assist the trier of fact in answering the relevant question of whether any products were actually impacted.

B. Expert Testimony of Dr. David Kessler on the Meaning of “Material Impact” Should Be Excluded As Both an Impermissible Legal Conclusion and Unreliable Personal Opinion

Plaintiffs offer the opinion of former FDA Commissioner David Kessler, J.D. / M.D, an expert whose opinions have been excluded under *Daubert* eight times in the past five years.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But, as other courts have held, the quintessential

legal term “material,” like other legal terms, is for the courts to interpret, not experts. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Courts exclude expert opinions that, like here, are simply the expert’s “*ipse dixit*” or say-so, rather than based on a professional standard or methodology.

[REDACTED]

[REDACTED]

1. Dr. Kessler’s Opinion on “Material Impact” is an Impermissible Legal Conclusion.

Courts generally, and the Third Circuit specifically, hold that defining or applying legal terms of art cannot be the subject of expert testimony. *Flickinger v. Toys R Us-Delaware, Inc.*, 492 F. App’x 217, 224 (3d Cir. 2012) (citing 4 Jack B. Weinstein & Margaret A. Berger, Weinstein’s Federal Evidence, § 704.04[1] (Joseph M. McLaughlin, ed., Matthew Bender 2d ed. 2011)). “The best way to determine whether opinion testimony [is unhelpful because it merely states] legal conclusions, ‘is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.’” *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002) (quoting *Torres v. Cnty. of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)). “Material” is just such a term with a “separate, distinct and specialized meaning in the law different from that present in the vernacular.” *SEC v. Goldstone*, No. 12-CV-0257 JB/LFG, 2016 U.S. Dist. LEXIS 61657, at *134 (D.N.M. May 10, 2016) (internal quotation marks and citation omitted). “[M]ateriality has a specialized legal meaning, and it is therefore within the [court’s] discretion to exclude such testimony.” *CSX Transp., Inc. v. Gilkison, Peirce, Raimond & Coulter, P.C.*, No. 5:05CV202, 2012 U.S. Dist. LEXIS 173152, at *11 (N.D.W. Va. Dec. 6, 2012) (excluding such an opinion) (internal quotation marks and citation omitted).

For this reason, expert opinions on materiality are regularly excluded from evidence. *See Feinberg v. Katz*, No. 01 Civ. 2739(CSH), 2007 U.S. Dist. LEXIS 94967, at *28 (S.D.N.Y. Dec. 21, 2007) (excluding certified public accountant’s opinion on materiality of omissions in financial statements because “[a]t trial, the Court, and not a witness, will instruct the jury on the law of materiality.”); *Hoefer & Arnett, Inc. v. Lehigh Press, Inc.*, Civ. No. 86-7016, 1988 U.S. Dist. LEXIS 2502, at *4 (E.D. Pa. Feb. 12, 1988) (excluding expert opinions addressing

materiality because the issue was a “question[] of law, to be charged by the court.”); *see also Goldstone*, 2016 U.S. Dist. LEXIS 61657, at *134-135 (excluding opinions of expert accountant on whether disclosures contained material misstatements); *Hill v. Equitable Bank, Nat’l Ass’n*, Civ. A. No. 82-220 CMW, 1987 WL 8953 (D. Del. Mar. 3, 1987) (expert testimony by law professor as to whether bank’s alleged omissions were material was inadmissible).

[REDACTED]

[REDACTED]

[REDACTED] Accordingly, Dr. Kessler’s opinion should be excluded.

2. Dr. Kessler’s Definition of “Material Impact” is Unreliable Personal Opinion

[REDACTED]

[REDACTED] An expert must, among other things, have “‘good grounds’ for his or her belief.” *In re Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590); *see also Oddi v. Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000) (“[T]he test is whether the particular opinion is based on valid reasoning and reliable methodology.”) (internal quotation marks and citation omitted). In considering whether there are “good grounds” for the expert’s opinions, the Third Circuit considers:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been ***subject to peer review***; (3) the known or potential rate of error; (4) ***the existence*** and maintenance ***of standards*** controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to ***methods which have been established*** to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the ***non-judicial uses to which the method has been put***.

In re Paoli, 35 F.3d at 742 n.8 (emphasis added). Dr. Kessler’s opinion fails the bolded factors.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But courts, again including the Third Circuit, reject this “say-so” or *ipse dixit* approach. *See Oddi*, 234 F.3d at 158 (expert’s baseless opinion as “*ipse dixit* does not withstand *Daubert*’s scrutiny.”); *Salazar v. United States*, Civ. No. 5:01-0617, 2003 WL 25695854, at *3 (S.D.W. Va. Feb. 18, 2003) (expert’s method unreliable when “created directly for use in this litigation”); *Pappas v. Sony Elecs., Inc.*, 136 F. Supp. 2d 413, 426 (W.D. Pa. 2000) (excluding expert opinion when expert failed to demonstrate that his method was used by other experts or cited in professional literature). As the Third Circuit has held, an expert opinion cannot be based on “subjective belief or unsupported speculation.” *In re Paoli*, 35 F.3d at 742 (citing *Daubert*, 509 U.S. at 590). Without any FDA regulatory standard or practice to ground Dr. Kessler’s opinion, it fails this test.

Perhaps because he served as Commissioner, Dr. Kessler has often confused the appropriate bounds of admissible expert testimony, and aspects of his expert reports or testimony have been excluded on *Daubert* grounds eight times in the last five years alone, including by one

court that did so because – as here – it was “based on his personal opinion, rather than any reliable basis.” *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 631 (S.D.W. Va. 2013).¹ It would contravene the gatekeeping purpose of *Daubert* to allow Dr. Kessler to opine based on nothing more than his say-so and for purposes of this lawsuit only [REDACTED]

C. The Expert Testimony of Dr. Matthew Perri Should Be Excluded Because His Opinions Are Unreliable and Unrelated to the Relevant Inquiries

The Court should exclude the expert testimony of Matthew Perri because his methods are unreliable, as another court has found when presented with a strikingly similar opinion.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But, like any expert, Dr. Perri must reach his conclusions using reliable methodologies, and tether his opinions to relevant factual inquiries.

Dr. Perri’s report and testimony fail to meet these fundamental requirements in two critical respects. First, Dr. Perri employed no definable or reliable methodology to reach these

¹ See also *In re Bard IVC Filters Prods. Liab. Litig.*, No. 2:15-MD-02641, 2017 U.S. Dist. LEXIS 210162, at *304 (D. Ariz. Dec. 21, 2017); Mem. and Order, *Bartolini v. Abbott Labs., Inc.*, No. 3:15-CV-00702 (S.D. Ill. May 23, 2017) [Dkt. 277]; Order Granting Motion to Exclude the Testimony of Dr. Kessler, *Western Sugar Coop. v. Archer-Daniels-Midland Co.*, No. 2:11-CV-03473, (C.D. Cal. Nov. 9, 2015) [Dkt. 680]; Order, *In re Prograf Antitrust Litig.*, No. 1:11-MD-02242 (D. Mass. Dec. 23, 2014) [Dkt. 648]; *Drake v. Allergan, Inc.*, No. 2:13-cv-00234, 2014 U.S. Dist. LEXIS 151830, at *14-16 (D. Vt. Oct. 23, 2014); *Allen v. Takeda Pharm. N.A., Inc.*, Nos. 6:11-MD-02299, 6:12-CV-00064, 2014 U.S. Dist. LEXIS 4808 (W.D. La. Jan. 10, 2014); *Wells v. Allergan*, No. 5:12-CV-00973, 2013 U.S. Dist. LEXIS 185373 (W.D. Okla. Feb. 4, 2013).

opinions. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Accordingly, Dr. Perri's report and testimony should be excluded.

"Reliability" is a critical touchstone of a *Daubert* analysis. *See In re Paoli*, 35 F.3d at 742. It requires that an expert use methods or techniques that are generally accepted in the expert's field. *Id.* Dr. Perri has run afoul of these requirements before, and for reasons nearly identical to those that exist here, had his expert report and testimony excluded. *See United States v. AseraCare Inc.*, No. 2:12-cv-245, 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014), holding *aff'd*, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014).

In *AseraCare*, the government offered Dr. Perri as a "marketing expert" to support its theory that an operator of hospice facilities knew it submitted false claims. [REDACTED]

[REDACTED] Perri claimed to base his opinion on "universal principles of marketing." The court excluded his testimony, finding that it failed to "meet[] the basic requirements of qualification, reliability, and helpfulness[.]" *Id.* at *11. The court stressed Dr. Perri's lack of experience in the hospice industry and emphasized that he "merely recite[d] the documentary evidence and testimony of former AseraCare employees regarding AseraCare's marketing and business practices, [and] then ma[de] conclusory statements about what AseraCare knew." *Id.* In

[REDACTED]

[REDACTED] For this reason as well, Dr. Perri's opinions must be excluded under Rule 702.

D. The Expert Testimony of Dr. Stephen Schondelmeyer Should Be Excluded Because He Offers No Reliable Methodology for His Economic Conclusions

To recover on their claims, plaintiffs must prove economic injury. To this end, plaintiffs posit that the At-Issue Drugs were worthless and proffer the expert testimony of pharmaceutical economist Stephen Schondelmeyer, Ph.D. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Dr. Schondelmeyer's Economic Opinions Lack Any Economic Analysis

Dr. Schondelmeyer's opinions are unreliable because they lack any methodology. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Third Circuit has upheld the exclusion of an expert because “he used little, if any, methodology beyond his own intuition.” *Oddi*, 234 F.3d at 158. Although Dr. Schondelmeyer’s opinion is not scientific, “he must still provide a methodology that can be proven to be reliable.” *Bethea v. Bristol Lodge Corp.*, Civ. No. 01-612, 2003 U.S. Dist. LEXIS 9011, at *19-21 (E.D. Pa. May 19, 2003). As an expert, Dr. Schondelmeyer must explain the means by which he reached his conclusions in order for those conclusions to be considered reliable. *See Wolfson-Verrichia Grp., Inc. v. Metro Commercial Real Estate, Inc.*, Civ. No. 08-cv-4997, 2013 U.S. Dist. LEXIS 44255, at *35 (E.D. Pa. Mar. 28, 2013) (excluding an expert’s testimony where “[t]he principal problem underlying [his] analysis is that there is no meaningful explanation as to how it was performed.”). As an economist, Dr. Schondelmeyer’s failure to use any economic analysis – or other reliable methodology – in forming his opinions renders them inadmissible.

2. [REDACTED]

An expert’s testimony is inadmissible if, as here, it speculates on a party’s intent, purpose, or motivations. Conclusions regarding a party’s intent, purpose, or motivations are outside the realm of permissible expert testimony and are properly left to the trier of facts. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (excluding expert testimony “on the intent, motives or states of mind of corporations, regulatory agencies and others [because they] have no basis in any relevant body of knowledge or expertise”). The *In re*

Diet Drugs Products Liability Litigation court excluded testimony on “corporate intent” because “[t]he question of intent is a classic jury question and not one for experts[.]” MDL No. 1203, 2000 U.S. Dist. LEXIS 9037, at *28-29 (E.D. Pa. June 20, 2000); *see In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding expert testimony on “the knowledge, motivations, intent, state of mind, or purposes of” various parties because such conjectures were “not a proper subject for expert or even lay testimony.”)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *see Bethea*, 2003 U.S.

Dist. LEXIS 9011, at *19-21 (excluding expert whose “analysis appears to be no more than his instinctive reaction to the materials provided.”). Dr. Schondelmeyer should know better as he has previously been precluded from testifying about a party’s “intent/state of mind.” *Healthpoint, Ltd. v. Ethex Corp.*, Civ. No. SA-00-CA-0757, 2001 WL 36101315, at *3 (W.D. Tex. Sept. 7, 2001) (“[P]roposed testimony [by Dr. Schondelmeyer] regarding the intent/state of mind of Healthpoint . . . shall also be excluded. Again, this is a question for the jury to decide.”)

Plaintiffs should not be allowed to supplant their own direct testimony with Dr. Schondelmeyer’s improper testimony on their mindset, [REDACTED]

In *Floorgraphics, Inc. v. News America Marketing In-Store Services*, the court excluded an expert who testified on the “likely opinions of retailers and supplier reactions to various practices allegedly initiated by Defendants” but failed to show evidence of any “company [that] stopped doing business with Plaintiff or reduced the volume of its business with Plaintiff because of Defendants’ conduct.” 546 F. Supp. 2d 155, 178 (D.N.J. 2008). The court found the plaintiff improperly sought to introduce “the testimony of [the expert] as a substitute for the direct testimony of individuals who have first hand knowledge of the events at issue.” *Id.* at 179.

[REDACTED] Defendant's Statement of
Undisputed Material Facts ¶¶ 55-57.

3. Dr. Schondelmeyer Fails To Connect His General Theories to The Facts in This Case

“[O]pinion evidence that is connected to existing data only by the *ipse dixit* of the expert” is inadmissible under *Daubert*. *Kumho*, 526 U.S. at 157 (internal quotation marks and citation omitted). Where an expert seeks to testify based on personal experience, courts must make certain that the expert would employ “the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.* at 152; *see WM High Yield Fund v. O’Hanlon*, Civ. No. 04-3423, 2013 U.S. Dist. LEXIS 90323, at *52-53 (E.D. Pa. June 27, 2013) (excluding testimony of an expert who offered “only his personal beliefs as to what could, would, and should have happened” because his opinions were “connected to existing data only by [his] *ipse dixit*.”) (internal quotation marks and citation omitted). Dr. Schondelmeyer failed to explain how he reliably applied his experience to the relevant facts in this case. [REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Schondelmeyer

has previously been criticized for this exact practice of ignoring contradictory record evidence.

See J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc., Nos. 1:01-cv-704, 1:03-cv-781, 2005 U.S. Dist.

LEXIS 11676, at *53 (S.D. Ohio June 13, 2005) (Schondelmeyer “ignore[d] substantial evidence

in the record that contradicts [his] assumption.”) Because Dr. Schondelmeyer’s opinion lacks

supporting evidence in the record, it amounts to mere speculation and must be excluded.

E. The Expert Testimony of Dr. Rena Conti Should be Excluded Because Her Opinion That the At-Issue Drugs are Worthless is Based on Legal Interpretation and Her Damages Calculation is Economically Flawed

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. [REDACTED]

Dr. Conti's opinion [REDACTED]

[REDACTED] must be excluded. Expert witnesses are prohibited from rendering opinions of law because such opinions usurp the court's role in explaining the law to the jury. *See Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006); *see also Krys v. Aaron*, 112 F. Supp. 3d 181, 192 (D.N.J. 2015) (excluding expert testimony that "unquestionably invades the Court's province by rendering a legal opinion"). This prohibition includes "testimony as to the legal effect of federal regulations" and as to the meaning and application of terms in a statute or regulation. *Jordan v. Temple Health Sys.*, Civ. No. 16-5561, 2018 U.S. Dist. LEXIS 128747, at *3 (E.D. Pa. Aug. 1, 2018); *see also In re Wellbutrin SR*

Antitrust Litig., Civ. Nos. 04-5525, 04-5898, 05-396, 2010 U.S. Dist. LEXIS 144271, at *13 (E.D. Pa. Mar. 31, 2010) (“[T]he expert is not permitted to opine on ‘what the law required.’”)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Dr. Conti Offers No Reliable Economic Methodology

Dr. Conti’s opinions should also be excluded because they lack any reliable economic methodology. The Third Circuit has upheld the exclusion of an expert because “[t]here [was] nothing [in the way of methodology] to submit to peer review, and it [was] impossible to ascertain any rate of error [for the method.]” *Oddi*, 234 F.3d at 158. The Third Circuit requires economists to meet these standards. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) (affirming exclusion of economist’s “damages opinion [as] not sufficiently reliable”).

² [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Here, except for seizing certain lots, FDA did not withdraw any At-Issue Drug from the market.

The image consists of 25 horizontal black bars of varying lengths, arranged in a list-like fashion. The bars are solid black and have no text or other markings. They are arranged in a way that suggests a redacted document, with some bars starting at the left margin and others indented. The lengths of the bars vary, with some being very short and others being nearly full-width. The bars are arranged in a single column, with no overlapping or gaps between them.

3. Dr. Conti's Opinions are Inadmissible to the Extent She Simply Parrots Plaintiffs' Allegations

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, this opinion does not pass muster with *Daubert* as it again lacks any analytical support.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Expert witnesses may not act as a mouthpiece for a party's argument, highlighting and interpreting record evidence. *See Alpha Pro Tech, Inc. v. VWR Int'l, LLC*, 2016 U.S. Dist. LEXIS 141030, at *13 (E.D. Pa. Oct. 12, 2016) (“[P]laintiff will not be permitted to have [its expert] serve as the mouthpiece for such argument”); *In re Rezulin Prods.*

Liab. Litig., 309 F. Supp. 2d at 551 (excluding expert testimony where it “does no more than counsel for plaintiff will do in argument”). [REDACTED]

4. Dr. Conti’s Damages Calculations Are Fundamentally Flawed

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Expert opinions must be grounded in the “real world” or the “economic reality” of the plaintiff. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000) (excluding expert who ignored the “real world” of the plaintiff); *see also Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) (trial court abused its discretion admitting expert’s opinion “because it did not incorporate all aspects of the economic reality of the . . . market”). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But, “[a]n instruction from counsel is not a sound basis on which to draw an economic conclusion.” *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 146 (E.D. Pa. 2015). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] When evaluating damages claims for prescription drugs, courts have rejected claims for the full price of drugs without deducting the cost of the therapeutic alternatives. *See Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014), *aff’d* 806 F.3d 71 (2d Cir. 2015) (“[O]ne cannot assume that the alternative to a Ketek prescription would be no prescription at all and permit Plaintiffs to recover the entire amount they expended on Ketek[.]”); *see also In re Celexa & Lexapro Mktg. and Sales Practices Litig.*, 325 F.R.D. 529, 540 (D. Mass. 2017) (agreeing that plaintiffs’ “damages calculations are flawed because they fail to consider the difference between what a consumer paid for the drug and the cost of an alternative medication.”). [REDACTED]

[REDACTED]. For example, if a patient had been using Avandia to treat diabetes and Avandia became unavailable, the patient most likely would not have stopped using medication but instead would have switched to another medication such as Actos. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

IV. CONCLUSION

For the foregoing reasons, GSK respectfully requests that the Court exclude opinions and testimony of Philip Russ, and Drs. David Kessler, Matthew Perri, Stephen Schondelmeyer, and Rena Conti as set forth herein.

November 7, 2018

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CERTIFICATE OF SERVICE

The undersigned attorney certifies that, on this date, he caused to be served copies of the foregoing upon counsel of record via the Court's CM/ECF system.

November 21, 2018

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